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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,903	12/08/2004	Catharina Svanborg	2491-49	7669
23117	7590	09/25/2006	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			ROOKE, AGNES BEATA	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

<b>Application No.</b> 10/506,903	<b>Applicant(s)</b> SVANBORG ET AL.	
<b>Examiner</b> Agnes B. Rooke	<b>Art Unit</b> 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 30 June 2006.
- 2a)  This action is **FINAL**.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-15 and 17 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1, 2, 4-7, 9, 10, 12 and 15 is/are rejected.
- 7)  Claim(s) 3, 8, 11, 13, 14 and 17 is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on 09/07/2004 is/are: a)  accepted or b)  objected to by the Examiner.
  - Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
  - Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All b)  Some \* c)  None of:
    - 1.  Certified copies of the priority documents have been received.
    - 2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    - 3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5)  Notice of Informal Patent Application
- 6)  Other: \_\_\_\_\_.

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### DETAILED ACTION

This non-final office action is in response to the paper filed on 06/30/2006. The amendments to the claims submitted on 06/30/2006 are acknowledged.

Claims 1-15 and 17 are pending. Claim 16 is cancelled. New claim 17 has been added.

This application is a 371 of PCT/IB03/01293, filed on 03/07/2003, which claims priority to UNITED KINGDOM 0205347.8, filed on 03/07/2002.

Examiner confirms that a certified copy of the foreign priority application has been received and on file since 09/07/2004.

**All objections and rejections not present in this office action have been withdrawn.**

### **REJECTIONS MAINTAINED**

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 5, 6, 9, and 10 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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In claims 1, 4, and 9, the Applicant refers to a fragment of  $\alpha$ -lactalbumin. These claims do not satisfy the written description requirement because the fragments do not have a necessary function, since these fragments do not have intrinsic characteristics by themselves. Thus, the structure of the fragments does not correspond with their function(s).

Also, claim 1, refers to a fragment of a variant of  $\alpha$ -lactalbumin. The variant of the  $\alpha$ -lactalbumin is not disclosed and thus unknown, therefore a fragment of a variant of  $\alpha$ -lactalbumin is also unknown, and the structure of the variant does not correspond with its function.

In claim 1, the Applicant refers to a biologically active complex comprising  $\alpha$ -lactalbumin or its variants or its fragments, and a cofactor which stabilizes that complex, where the cofactor is other than C:18:1:9 cis fatty acid. On page 15 [not page 51 as previously cited by examiner] of the specification, lines 20-29, the Applicant refers to Figure 1, which shows simplified fatty acid structures that were investigated for their ability to produce a HAMLET like molecular complex. However, no examples of cofactors, other than C:18:1:9 cis fatty acid are presented in the claim. Therefore, the structures of other cofactors should be provided, otherwise the structure of undisclosed cofactors do not correspond with their function.

In claims 1, 4, 5, 6, 9, 10, the Applicant refers to variant of  $\alpha$ -lactalbumin. The variants are not disclosed, and thus the structure of the variants does not correspond with their function and the written description requirement is not satisfied.

In claim 9, an appropriate SEQ ID NO should be provided in the claim to examine the claim accordingly.

Applicants responded that the sequence of albumin is known and therefore it is not necessary to include it in the claims and that the specification further describes the claimed fragments in [0022-0023], and the recited region which forms the interface between the alpha and beta domains is described in [0033]. Moreover, Applicants point out that the specification describes the required biological activity of the claimed complex in [0019].

Examiner acknowledges the explanation but still maintain the rejection because specific fragments claimed and the appropriate reference to the full sequence of the fragment must be included in the claims in issue.

Further, Applicant states that cofactors are adequately described in the specification, see [0046], and that as claim 1 provides, when the complex comprises full length  $\alpha$ -lactalbumin in which the calcium binding site has been modified so that the affinity for calcium is reduced, or it is no longer functional, the cofactor is other than C18:1:9 cis fatty acid. Further, Applicants correctly pointed out that there is no page 51 in the specification. Examiner apologize for the typo and states that the correct page number should be 15, and not 51 (see above).

Examiner maintains the rejection of claim 1 regarding the undisclosed cofactors because the structures of cofactors "other than C:18:1:9 cis fatty acid" should be provided in the claim.

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Further, Applicants discuss variants of  $\alpha$ -lactalbumin that are described in [0020] and that the preferred examples of the claimed variants are described in [0024-0032].

Examiner responds that claimed variants should be disclosed in the claims since the structure of the variant claimed must correspond to its function.

Moreover, Applicants stated that SEQ ID NO in claim 9 is not necessary.

Examiner disagrees and requires the SEQ ID NO in claim 9 since the claim refers to a fragment of  $\alpha$ -lactalbumin that includes region from 34-86 amino acids of the native protein, as thus proper reference to the SEQ ID NO is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 7, 9, 12, and 15 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 7 and 9, the Applicant refers to a complex which "comprises a fragment of  $\alpha$ -latalbumin or a variant thereof, and where the fragment includes the entire region from amino acid 34-86 of the native protein." However, a SEQ ID NO that would provide reference to the claimed positions of amino acids 34-86 is not provided, and thus the claim is indefinite. Thus, the appropriate SEQ ID NO must be provided in the claim, since specific amino acid positions are claimed in reference to an unknown SEQ ID NO.

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Applicants responded that metes and bounds of the claim would be understood by one skilled in the art and thus the reference to the SEQ ID NO is unnecessary.

Examiner disagrees and maintains the rejection because SEQ ID NO of the full sequence at issue is necessary in the claim.

In claim 12, the name of an "S70R" mutation must be fully spelled out. Further, there is no reference to S70R in the specification, thus the claim cannot be adequately searched. Also, claim 12 should depend from claim 10.

Claim 15 would still be indefinite, since the structure of the complex from claim 1 cannot be ascertained.

### **NEW REJECTION**

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2 it states that "a complex according to claim 1 wherein the cofactor is a cis C18:1:9" where claim 1 states that "the cofactor is other than C18:1:9 cis."

Therefore, claim 2 lacks antecedent basis to claim 1.

**NEW OBJECTIONS**

Drawings objected to in the specification include: Figure 2 where it should state: Figure 2A-H; Figure 3 where it should state: Figure 3 A and 3B; Figure 4 where it should state: Figure A-H; Figure 5 where it should state: Figure 5 A-H; Figure 7 where it should state: Figure 7 A-C; Figure 8 where it should state: Figure 8A and Figure B; Thus appropriate corrections are required in the text of the specification.

New claim 17 should start with a capital letter.

Claims 3, 8, 11, 13, and 14 are objected to because they depend from rejected independent claim.

**Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

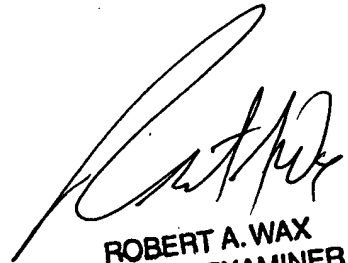
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